

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/17/2010 has been entered. New claim 42 has been added.

Applicant's arguments filed 08/17/2010 and 09/01/2010 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

The previous final rejection dated 09/15/2010 has been vacated.

Claim Rejections - 35 USC § 103

Claims 23, 24, 26, 27, 30-32, 34, 35, 38, 39, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oniki et al. (WO 03/030851) in view of Takeda et al. (US 2001/0007652) as evidenced by Sharma et al. (Def. Sci. J., 1983).

Oniki et al. teach a method of making teeth look whiter by causing a whitening component to infiltrate into the tooth enamel, thereby changing the optical properties of the enamel without chemical reactions (page 1, lines 8-15, page 2, lines 33-37). The method reversibly makes teeth look apparently cloudy and whiter (page 3, lines 1-7). The whitening component is one or more selected from lower alcohols having four or less carbon atoms, such as ethanol, isopropyl alcohol, n-propanol and n-butanol; glycols having ten or less carbon atoms such as propylene glycol, diethylene glycol, ethylene glycol, dipropylene glycol and 1,3-butylene glycol; polyethylene glycols, such as those having a molecular weight of 200-800; glycerin and diglycerin (page 4, lines 15-29). The whitening component can be used in conjunction with water in a ratio as high as 100/0, i.e. no water (page 5, lines 7-11). The amount of whitening component should preferably be 20% to 100% of the entire composition (page 5, lines 19-20). The tooth whitening composition is comprised of a gelling agent such as carboxymethylcellulose in amounts from 0.1 to 15% (page 6, lines 8-13). The whitening composition is incorporated with surfactants such as sodium lauryl sulfate in amounts from 0.1 to 10% (page 6, lines 27-31). The whitening composition should preferably be applied to teeth in concert with a special tool which retains and keeps it in position in

contact with teeth, prevents the composition from dissolving and dilution by saliva and eliminates unpleasant feeling. It may be formed from a water-insoluble material in the form of a tape, sheet or film (page 8, lines 24-36). The tools should be formed from materials such as polyethylene, foamed polyethylene, polypropylene, polyester, rayon, pulp, cotton, silk and paper (page 9, lines 13-15). The duration of application is 1 to 120 minutes per dosage (page 10, lines 9-12).

Oniki et al. does not teach that the composition is further comprised of a substance (B).

Takeda et al. teach a dentifrice composition for imparting gloss on teeth comprising shellac; when the composition is used the whiteness inherent in teeth can be given to the teeth, and good gloss, brightness and luster can be further imparted on teeth due to the prevention of the irregular reflection of light by a coating of shellac (Abstract, [0039]), i.e. shellac changes the optical properties of teeth. The composition can be in the form of a gel [0007], [0016]. The content of shellac is 0.01% to 10% [0013]. The composition comprises propylene glycol and/or glycerin [0018]. Thickening agents such as sodium carboxymethylcellulose are used in the compositions [0017]. The shellac is dissolved in conventional dentifrice substances such as propylene glycol [0018]. Foaming agents such as sodium lauryl sulfate may be included in the composition in amounts of 1.5% by weight [0017] and [0025]. No particular limitation is imposed on the usage of the dentifrice compositions [0019]. As evidenced by Sharma et al., shellac is comprised of gallic acid and gallic acid, i.e. 9,10,16-trihydroxypalmitic acid with ester or lactone linkage, page 262, last paragraph.

Takeda et al. does not teach the specific amount of propylene glycol.

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly, it would have been obvious to combine the shellac in the weight ratios of Takeda with the composition of Oniki et al. in order to form a third solution that also changes the optical properties of teeth and makes teeth appear white.

At the time of the invention, it would have been obvious to modify the composition to be comprised of propylene glycol as the whitening agent, since Takeda et al. teach that the shellac is dissolved in propylene glycol when producing the composition, and Oniki et al. teach its incorporation as the whitening agent. It would assure that the shellac is dissolved as required by Takeda et al., which would allow it to infiltrate into the tooth enamel along with the propylene glycol, thereby changing the optical properties of the enamel as taught by Oniki et al.

In regards to claims 23, 31, 39, 41 and 42, the prior art does not teach the specific amounts of the tooth whitening ingredient, A. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Oniki et al. teach from 20% to 100% of the whitening ingredient versus 50.0 to 99.5% of the instant claims.

Response to Applicant's arguments and Affidavit

Applicant argues that the Takeda dentifrice composition contains significant amounts of water as an essential component. All the working examples of Takeda are more water based. Therefore, should one of skill in the art actually combine the disclosure of Takeda and Oniki, this would lead to a composition containing water, and thus not the instantly claimed nonaqueous gel. The Takeda and Oniki compositions/methods involve large amounts of water. As a result, the shellac of Takeda is not properly dissolved, and thus cannot penetrate into the enamel of teeth. Takeda merely coats the teeth to give a whitening effect which does not last for a long time. Applicant cites paragraph [0018] of Takeda as evidence that shellac dissolves in substances commonly used in the conventional dentifrice compositions such as propylene glycol. Since a considerable amount of water is present in the dentifrice composition of Takeda, shellac is not dissolved, but is present as an undissolved solid or paste in the resulting dentifrice composition; and the compound which is able to dissolve shellac such as propylene glycol is only present in an insufficiently small amount.

The Examiner disagrees.

Since the rejection is a 103 obviousness rejection, neither Takeda nor Oniki is required to teach each and every limitation of the instant claims. Further, the working examples are not representative of the entire scope of the specification. Oniki et al. is

the primary reference in the rejection and Takeda et al. is only cited to disclose the use of shellac as a component that can change the optical properties of teeth. As cited *supra*, Oniki clearly discloses that the whitening component is one or more selected from lower alcohols having four or less carbon atoms, such as ethanol, isopropyl alcohol, n-propanol and n-butanol; glycols having ten or less carbon atoms such as propylene glycol, diethylene glycol, ethylene glycol, dipropylene glycol and 1,3-butylene glycol; polyethylene glycols, such as those having a molecular weight of 200-800; glycerin and diglycerin. **The whitening component can be used in conjunction with water in a ratio as high as 100/0, i.e. no water.** The amount of whitening component should preferably be 20% to 100% of the entire composition. Accordingly, Oniki et al. discloses nonaqueous compositions comprised of propylene glycol in amounts preferably from 20% to 100%. The paragraph cited by Applicant only provides motivation for using nonaqueous compositions comprised of propylene glycol, i.e. propylene glycol/water ratio of 100/0, when incorporating the shellac of Takeda et al. with the composition of Oniki et al. As cited *supra*, Takeda et al. disclose that gels, pastes and liquids are possible forms of the dentifrice. Takeda et al. also disclose that the composition is mixed into a uniform viscous liquid and into a uniform toothpaste, see Takeda [0022]. It would reasonably be assumed that the gels and liquids would also be uniform dentifrices without undissolved shellac present.

Applicant argues that the shellac of Takeda et al. does not infiltrate the enamel of teeth. It may cover the surface of teeth in a pasty state, which also prevents infiltration of polyols. The precipitated shellac or wax on the surface of teeth is brittle and easily

removed from the surface of teeth. Thus, the whitening effect does not endure for a long time.

The Examiner disagrees.

As cited *supra*, Oniki et al. discloses nonaqueous compositions comprised of from 20% to 100% propylene glycol. Takeda et al. discloses that the numerous flaws on teeth cause their brightness to be lessened; and that the shellac covers the surface of teeth, thereby smoothing them, see Takeda et al. [0039]. One of ordinary skill would reasonably expect that the shellac of Takeda et al. fills in the flaws on enamel of teeth to provide a smooth covering, when applied as a gel. Further, as cited *supra*, the disclosure that shellac changes the optical properties on teeth provides adequate motivation for incorporating it in the composition of Oniki et al. since they both are used for the same purpose. When incorporating of the shellac of Takeda et al. into compositions of Oniki et al. one of ordinary skill would reasonably take the disclosure of paragraph [0018] of Takeda et al. cited by Applicant and provided *supra* into consideration and prepare compositions comprised of propylene glycol in order to dissolve the shellac. Since the shellac would be dissolved in the propylene glycol, both propylene glycol and shellac would reasonably be expected to infiltrate the flaws of the enamel, especially with the disclosure of Oniki that the whitening components of the composition infiltrate the tooth enamel. Accordingly, the compositions/methods suggested by combining Oniki et al. and Takeda et al. read on the claimed invention; and would reasonably be expected to reversibly make teeth look white. There is no limitation in the instant claims as to the length of time of the whitening effect.

Applicant argues that Takeda fails to disclose or teach the application of the nonaqueous gel composition by using the special tool of the inventive set and method and feature thereof as instantly claimed.

The Examiner disagrees.

As cited *supra*, Oniki et al. is the primary reference and Takeda et al. is only cited to disclose the use of shellac as a component that can change the optical properties of teeth. Oniki et al. disclose that the whitening composition should preferably be applied to teeth in concert with a special tool which retains and keeps it in position in contact with teeth, prevents the composition from dissolving and dilution by saliva and eliminates unpleasant feeling. It may be formed from a water-insoluble material in the form of a tape, sheet or film. The tools should be formed from materials such as polyethylene, foamed polyethylene, polypropylene, polyester, rayon, pulp, cotton, silk and paper. The duration of application is 1 to 120 minutes per dosage. Accordingly, once motivation is provided for incorporation of the shellac of Takeda et al. into the compositions of Oniki et al. it would have been obvious to use the methods of Oniki et al. to apply the modified compositions.

Applicant argues since the cited references use aqueous compositions, that there is improper rationale for combining the references since the shellac would not properly dissolve.

The Examiner disagrees.

The Examiner's response to Applicant's arguments concerning aqueous compositions is provided *supra*.

Applicant argues that Oniki is improperly combined with Takeda since it fails to disclose the use of the ingredient B. However Takeda fails to disclose the acrylic acid copolymers of the ingredient B, therefore the use of the acrylic copolymers as the ingredient of B are not expected from Takeda. The amount of polyols in Takeda et al. is fewer than the amount of the inventive tooth whitening set/method.

The Examiner disagrees.

As cited *supra*, adequate motivation has been provided for incorporating the shellac of Takeda et al. into the compositions of Oniki et al., which are comprised of from 20%-100% of polyol. Further, as cited *supra*, shellac is comprised of hydroxypalmitic acid, i.e. a C₁₆ fatty acid. The claims are drawn to "at least one C₁₄₋₂₂ higher fatty acid and/or acrylic acid copolymer". Accordingly, the shellac of Takeda et al. read on the limitations of the claim.

Applicants allege that the present invention has achieved unexpected and superior results in terms of the whitening effect and duration thereof. Applicant cites the Declarations filed 08/17/2010 as evidence of said allegation. Applicant argues that whiteness is achieved in differently than in the cited art and provides a depiction illustrating the mechanism of action of the instant invention.

The Examiner disagrees.

As cited *supra*, Oniki et al. clearly disclose that the whitening component of the compositions infiltrate the tooth enamel; and discloses propylene glycol as a whitening component in amounts from 20% to 100%. Accordingly, if the shellac of Takeda et al. is

incorporated into the composition of Oniki et al. it would reasonably be expected to be dissolved in the propylene glycol and infiltrate the tooth enamel also.

Applicant allege that the instant compositions provide superior results over working examples of Takeda and Oniki and directs the Examiner to Table 1 for evidence of said allegation.

Table 1 is not persuasive. The composition of Takeda et al., i.e. Comparison 1, is comprised of only 8% propylene glycol and 3% glycerin, i.e. 11% polyol. Since Oniki et al. disclose that propylene glycol and glycerin are both whitening components that change the optical properties of teeth in amounts of 20% to 100%, it would be reasonably expected that a composition comprised of only 11% polyols would not possess the whitening effect of one comprised of 98%, i.e. invention 1, and 89%, i.e. invention 2, of the whitening component and the whitening effect would reasonably be expected to last longer. Similarly, the composition of Oniki, i.e. Comparison 2, is not comprised of shellac. Since, Takeda et al. discloses that shellac changes the optical properties of teeth, it is not unexpected that a composition comprising of 98%, i.e. invention 1, and 89%, i.e. invention 2 of the whitening component along with shellac would provide enhance whitening effect over a composition comprised of 10% isopropanol and 30% propylene glycol, i.e. 40% whitening components, and that the whitening effect would last longer.

After analyzing, even assuming *arguendo* that unexpected results have been shown, the claims would not be commensurate in scope with those findings. In Table 1, Applicant has only used 93% propylene glycol, Invention 1, and 89% propylene glycol,

i.e. Invention 2, not any tooth whitening ingredient selected from isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-360, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol, and glycerin, not polyethylene glycol with an average molecular weight of 190-360, butylene glycol, and glycerin, not any ingredient having a relative permittivity of 17.0 to 43.0 (at 25°) and a vapor pressure of 0 to 7000 kPa, and not in any amount from 50% to 99.5%; has only used 1% Eudragit L100 and 5% shellac respectively, not any substance selected from myristic acid, 7-hydroxymyristic acid, jalaric acid, 9,10,16-trihydroxypalmitic acid, palmitoleic acid, 12-hydroxystearic acid, isostearic acid, oleic acid, linoleic acid, linolenic acid, erucic acid, shellac, t-Bu acrylate/ethyl acrylate/methacrylate acid copolymer, methyl acrylate/methacrylic acid copolymer, methyl methacrylate/methacrylic acid copolymer, acrylic acid/acrylamide/ethyl acrylate copolymer, octylacrylamide/acrylate ester copolymer, and methyl methacrylate/ethyl acrylate/methacrylic acid triethyammonium ethyl chloride copolymer, not any one selected from isostearic acid, shellac, t-Bu acrylate/ethyl acrylate/methacrylate acid copolymer, acrylic acid/acrylamide/ethyl acrylate copolymer, octylacrylamide/acrylate ester copolymer, and methyl methacrylate/ethyl acrylate/methacrylic acid triethyammonium ethyl chloride copolymer, not at least one selected from and C_{14-C22} higher fatty acids and/or acrylic acid copolymers, and not in any amount from 0.1 to 10%; and has only used 6% hydroxypropyl cellulose in both Invention 1 and Invention 2, not any gelling agent, not any gelling agent selected from polyacrylic acid, carboxyvinyl polymer, hydroxypropyl cellulose, carboxymethylcellulose and salts thereof, and not in any amount from 0.1 to

15%; has only used a polyurethane film, not any material selected from polyethylene, foamed polyethylene, polypropylene, foamed polypropylene, polyester, rayon, polyurethane, pulp, cotton, silk, paper, metal foil, silicone rubber, natural rubber, vinyl acetate resin, acrylic resin, and ethylene-vinyl acetate resin; and has only applied the composition to teeth for 3 minutes, not any time between 1 and 120 minutes. Accordingly, the scope of the claims is much broader.

The remainder of Applicant's arguments from the Declaration have been address *supra*.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
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